HFI-3?

#16946

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1123057

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

November 22, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Allen Carson, CEO
Greenbrier Respiratory Care Services, Inc.
175 North Seneca Trail
Fairlea, West Virginia 24902

Dear Mr. Carson:

An inspection of your facility was conducted by a representative of the state of West Virginia under contract to the Food and Drug Administration (FDA) on October 8, 1996. During the inspection, deviations from the Current Good Manufacturing Practice (GMP) Regulations [Title 21, Code of Federal Regulations (CFR), Parts 210 & 211] were observed. These deviations cause your Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations included the following:

1. Failure to adequately test each batch of Oxygen, U.S.P. for conformance to final specifications for the drug product prior to release. Your firm failed to test at least one cylinder from each manifold filling sequence. [21 CFR 211.165(a)]

2. Failure to establish written procedures for the calibration of gauges, i.e., thermometers, etc., used during the transfilling of Oxygen, U.S.P. and to maintain written records of those calibration checks. [21 CFR 211.68]

3. Failure to establish written procedures designed to reconcile the quantities of labeling issued, used, and returned. [21 CFR 211.125(a)]

4. Failure to establish adequate written procedures for the production and process controls, designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess, including procedures covering pre-fill, fill, and post-fill operations. [21 CFR 211.100(a)]

5. Failure to perform adequate pre-fill, fill, and post-fill operations on each high-pressure cylinder filled. Your firm failed to perform the hammer and temperature tests on each cylinder filled. [21 CFR 211.84(d)(3)]

6. Failure to establish adequate batch production and control records for each batch of Oxygen, U.S.P., including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance. Your firm's batch production records lacked the pre-fill, fill, and post-fill operations performed on each cylinder filled. Additionally, batch records were not endorsed by a person directly supervising or checking each significant step in the operation. [21 CFR 211.188(b)]

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the current Good Manufacturing Practice Regulations to medical gas manufacturers.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,

Kenneth C. Shelin

Kenneth C. Shelin
Director, Baltimore District

Enclosure

bcc: EI file, HFR-MA1, HFR-MA200, HFR-MA240 (Simmons), HFR MA250, HFA 224, HFC-210, HFI-35 (purged), HFC-240, HFD 300, HFR MA2545, HFR MA2530, HFR-MA295

Mr. Dennis Carroll
Associate Regional Administrator
HCFA
Room 3100
3535 Market Street
Philadelphia, PA 19101 (purged)

West Virginia Board of Pharmacy
236 Capitol Street
Charleston, WV 25301 (purged)

Bureau For Public Health
Office of Environmental Health Services
815 Quarrier Street, Suite 418
Charleston, WV 25301-2616 (purged)

Tracking No.: 97-BLT-9